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世佳电子有限公司
Sejoy Electronics & Instruments Co., Ltd.

510(k) Summary

JUL 18 2012

The assigned 510(k) number is: _____

1. Date Prepared:

2011.11.25

2. Submitter's Identification:

Name: Sejoy Electronics & Instruments Co., Ltd.
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3. Name of the Device:

Trade Name: Wrist-type Fully Automatic Digital Blood Pressure Monitor
Including the following models:
- BP-201M, BP-202H, BP-202N, BP-2206, BP-2208
Common Name: Blood Pressure Monitor
Classification name: Non-invasive blood pressure measurement System
21 CFR 870-1130, Class II, 74-DXN.

4. Classification Information:

Regulation Number: 870.1130
Product Code: DXN
Device Class: II
Panel: 74 Cardiovascular

5. Predicate Device Information:

The Wrist-type Fully Automatic Digital Blood Pressure Monitors are substantially equivalent to the following device:

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AM/PM Memory Wrist Blood Pressure Monitor (Model: UB-512), FDA 510(k) K042967, distributed by A division of A&D Engineering, Inc.

6. Device Description:

The wrist-type fully automatic digital blood pressure monitors uses an inflatable cuff which is wrapped around the patient's wrist. The cuff is inflated automatically by an internal pump in the device. The systolic and diastolic blood pressures are determined by oscillometric method and silicon integrate pressure sensor technology. The deflation rate is controlled by a preset mechanical valve at a constant rate. The pressure of the cuff is completely released automatically at the end of the measurement. At the same time, the measurements are displayed on the LCD display for three minute. There is a maximum pressure safety setting at 300 mmHg. The device will not inflate the cuff higher than 300 mmHg. For BP-202H, BP-2206, BP-2208, the blood pressure results are compared with WHO (World Health Organization) Blood Pressure classification, which are severe Hypertension, Moderate Hypertension, Mild Hypertension, High-normal, Normal, and Optimal. The corresponding LCD segment will be turned on along with the systolic, diastolic, and pulse rate information. BP-202H, BP-2206, BP-2208 will display an irregular heartbeat symbol "♥" if an irregular heartbeat was detected during the measurement process. BP-2208 can display average results in three ways: the average of all measurements, the average of all AM (5:00 AM-8:59AM) measurements, and the average of all PM (18:00 PM-19:59 PM) measurements. BP-202H, BP-2206 can calculate the average of the last three measurements. In addition, BP-2208 have LCD backlight. After three minutes without operation, the blood pressure monitors turn off automatically.

The detail comparisons among devices are listed below:

Features / Models	A	B	C	D	E	F	G	H	I	J	K
BP-201M	•	120 Memories	•	○	○	○	○	76×67.5×28.5	13.5-21.5 cm	45×30	○
BP-202N	•	120 Memories in four groups	•	○	○	○	○	76×67.5×28.5	13.5-21.5 cm	45×30	○
BP-202H	•	120 Memories in four groups	•	○	•	•	•	76×67.5×28.5	13.5-21.5 cm	45×30	○
BP-2206	•	120 Memories in two groups	•	○	•	•	•	77×64×32.5	13.5-21.5 cm	45×30	○
BP-2208	•	120 Memories in two groups	•	•	•	○	•	77×64×32	13.5-21.5 cm	49×38	•

A = Powered by 2 AAA batteries

B = Memory Size

C = Time & Date

D = Results Average in Three way
E = WHO (World Health Organization) Classification Indicator
F = Last 3 Results Average
G = Irregular Heartbeat Detection
H = Outside Demission (L x W x H in mm)
I = Cuff Size
J = LCD Size (Viewing Area in mm)
K = LCD Backlight
● = Yes
o = No

The devices are all designed and manufactured according to ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/A2:2006/(R) 2008, manual, electronic or automated sphygmanometers.

7. Intended Use:

The Wrist-type Fully Automatic Blood Pressure Monitors BP series are intended for used by adults with 12 years and older to measure the systolic and diastolic blood pressure and pulse rate.

The intended user and the indication for use of the Wrist-type Fully Automatic Blood Pressure Monitors BP series as described in the labeling are nearly the same as their predicated devices, AM/PM Memory Wrist Blood Pressure Monitor (Model: UB-512).

8. Summary comparing technological characteristics with predicate device:

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar
Biocompatibility	Identical
Mechanical Safety	Identical
Energy Source	Similar
Standards Met	Identical
Electrical Safety	Identical
EMC	Identical
Function	Similar

The difference of technological characteristic between the predicate device and the submit

wrist-type fully automatic blood pressure monitors is the appearance, the performance and the function.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards including ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/A2:2006/(R) 2008 as well as IEC/EN 60601-1: 2005+CORR.1 (2006) +CORR.2 (2007) / EN 60601-1:2006 /AC: 2010, IEC/EN 60601-1-2:2007, ISO 10993-5: 2009 Biological evaluation of medical devices —Part 5:Tests for in vitro cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.

Guidance documents include the "FDA Non-invasive Blood Pressure (NIBP) Monitor Guidance" and "FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "FDA Bluebook Memorandum G95-1Use of International Standard ISO 10993."

Non-clinical Tests:

- Electromagnetic Compatibility Test according to IEC/EN 60601-1-2:2007
- General Safety Provisions Test according to IEC/EN 60601-1: 2005+CORR.1 (2006) +CORR.2 (2007) / EN 60601-1:2006 /AC: 2010
- Performance Test according to ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/A2:2006/(R) 2008.
  The test result all meet or exceed the requirement of the standards.
- Biocompatibility Test according to FDA Bluebook, Memorandum G95-1Use of International Standard ISO 10993, ISO 10993-5: 2009 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization.

10. Discussion of Clinical Tests Performed:

Clinical tests were performed and complied the accuracy requirements of ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/A2:2006/(R) 2008 "National Standard for Manual, Electronic or Automated Sphygmomanometers".

11. Conclusions:

Our Wrist-type Fully Automatic Blood Pressure Monitor BP-201M, BP-202H, BP-202N, BP-2206, BP-2208 have the same intended use and similar technological characteristics as the

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A & D AM/PM Memory Wrist Blood Pressure Monitor (Model: UB-512) whose 510 (k) number is K042967.

Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared devices.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device, and the new models as mentioned on this submission are considered substantial equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 18 2012

Sejoy Electronics & Instruments Co., Ltd.
c/o Mr. Edmondo Roark
1259 Monten Street #4
Cincinnati, OH 45208

Re: K121355
Trade/Device Name: Wrist-type Fully Automatic Digital Blood Pressure Monitor
(Five Models: BP-201M, BP-202H, BP-202N, BP-2206, BP-2208)
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: II (two)
Product Code: DXN
Dated: April 6, 2012
Received: May 4, 2012

Dear Mr. Roark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

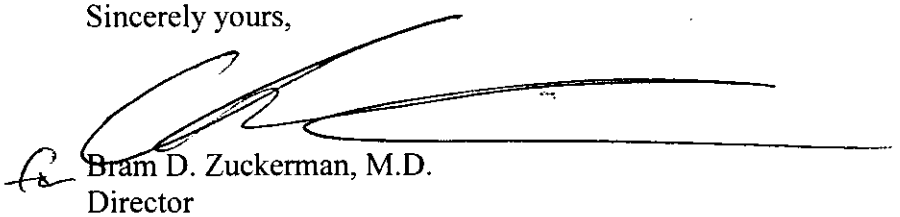
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K121355

Device Name: Blood Pressure Monitors BP series

Indications For Use:

Measure blood pressure (systolic and diastolic) and pulse rate.

Prescription Use_____ **AND/OR** **Over-The-Counter Use** √
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121355